

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Stephen D. Pacetti	Examiner: Loan H. Thanh
Serial No. 09/406,473	Art Unit: 3763
Filed: September 27, 1999	
Title: Drug Diffusion Barriers For A Catheter Assembly	

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REPLY BRIEF**

Sir:

On December 4, 2006, applicant appealed to the Board of Patent Appeals from the nonfinal rejection of Claims 139-154 which have been twice rejected. On March 20, 2007 Applicant filed an Appeal Brief. On May 7, 2007, the USPTO mailed a Notification of Non-Compliant Appeal Brief. On June 7, 2007, Applicant filed a Response to Notification of Non-Compliant Appeal Brief and an Amended Appeal Brief. On October 10, 2007, the Examiner mailed an Answer to which this Reply Brief is directed.

**Status of Claims**

Claims 139-154 are pending and have been twice rejected by the Examiner.

Claims 142, 143, and 147 form the subject of this appeal.

Claims 1-138 have been canceled.

**Grounds of Rejection to Be Reviewed on Appeal**

Issue 1: Whether Claim 142 is obvious over Sanhatjian et al. (U.S. Patent 5,674,192) (“Sanhatjian”) under 35 U.S.C. § 103.

Issue 2: Whether Claim 143 is obvious over Sanhatjian under 35 U.S.C. § 103.

Issue 3: Whether Claim 147 is obvious over Sanhatjian under 35 U.S.C. § 103.

## **Arguments**

**It is not inherent that the properties of the sheath material in the Examiner's prior art are the same as Applicant's claims**

On page 6, third full paragraph of the Examiner's Answer, the Examiner argues that the Applicant "has claimed (see claim 142-143, 145, 151) and specified in his specification this sheath material to be a polyurethane and since the Examiner's prior art teaches the sheath to be the same material, it is inherent that the properties would also be the same as appellant's claims." Applicant's arguments in the Appeal Brief demonstrate that the claimed sheath material in claims 142 and 143 is not the same material disclosed in Sanhatjian. Sanhatjian discloses a broad genus, "polyurethane;" a species of polyurethane, "Tecoflex™"; and Teflon® (not a polyurethane). (Col. 6, lines 62-63, Sanhatjian). As reiterated below, Applicant demonstrates on pages 3-5 of the Appeal Brief that the recited limitations of claim 142 are not inherent. With respect to claim 143, the Examiner has provided no argument or evidence that the limitations of said claim are inherent.

**Examiner has no basis for the assertion that it would be "obvious to one of ordinary skill in the art to substitute" the materials claimed in claims 142 and 143 for the sheath material in Sanhatjian**

On page 7, paragraph 1 of the Examiner's Answer, the Examiner states that "appellant's laundry list of materials appear to be substitutes of different materials which are interchangeable as described in appellant's specification ... This is further evidence that the appellant's choice of material is not critical, thus it would further be obvious to

one of ordinary skill in the art to substitute any material that is known for the intended use or suitability of the material.”

The Examiner fails to specify a “laundry list” in Applicant’s specification and to which claims it pertains. The Examiner appears to be referring to exemplary barrier polymers disclosed on pages 9-12 of Applicant’s specification and polymers claimed as members of Markush groups. The Examiner has no basis for the assertion that it would be “obvious to one of ordinary skill in the art to substitute” the materials claimed in claims 142 and 143 for the sheath material in Sanhatjian.

Such assertion directly contradicts the position of patent office procedure and case law. According to MPEP § 2144.06 II, “in order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant’s disclosure.” There is no prior art disclosure in the record that demonstrates that the claimed polyurethanes in claims 142 or 143 are equivalent. Furthermore, MPEP § 2144.06 II also states that “the mere fact that components are claimed as members of a Markush group cannot be relied upon to establish the equivalency of these components.” *Ibid.*

Additionally, Applicant discusses the limitations of claims 142 and 143 at page 10, line 23 to page 11, line 2 of Applicant’s specification. Applicants do not disclose a “laundry list” of polymers having such limitations.

**The limitations of claim 142 are not inherent**

On page 7, paragraph 2 of the Examiner’s Answer, the Examiner argues that “it is inherent that if Appellant claims polyurethane, and the prior art discloses polyurethane that it would meet the limitation and have the same properties such as that of the glass

transition temperature.... Further, all materials have Tg. Appellant has not specified what the Tg or the storage temperature, thus in the broadest interpretation since the device of the prior art discloses the same material (polyurethane) that the appellant is claiming it would be inherent that the prior art has the same properties as well lacking any further structurally distinguishing features.”

As pointed out on page 3, paragraph 2 of the Appeal Brief, the Examiner’s inherency theory is based on two grounds, both of which Applicant has demonstrated are without merit. The first ground, again reiterated in the above paragraph, is that it is inherent that the polyurethane of Sanhatjian has a glass transition temperature (Tg) that is above storage temperature because the storage temperature can be “any temperature.” According to MPEP § 2111, the Examiner must give the claims their broadest reasonable interpretation consistent with the specification. Applicant submits that a skilled artisan knows how to pick reasonable storage temperatures for medical devices based on the devices’ constituency and intended use. The Applicant is not “arguing more narrowly than claimed” as indicated by the Examiner. The Examiner has ignored Applicant’s recitation of the correct standard for claim construction.

Based on a reasonable interpretation of storage temperature, Applicant further demonstrates on pages 3-5 of the Appeal Brief that the recited limitations of claim 142 are not inherent. As explained in the Appeal Brief, a single example on the record contrary to the Examiner’s inherency theory precludes finding that a characteristic is inherent in the prior art. Specifically, extrinsic evidence in the National Textile Article cited in the first paragraph of page 4 of the Appeal Brief shows that the Tg of a

polyurethane, a medical grade Tecoflex®, is not above a reasonable storage temperature, unequivocally disproving the Examiner's inherency theory.

Moreover, the statement in the Examiner's Answer that the Examiner has not relied on the disclosure of Tecoflex® is irrelevant. Applicant has merely cited Tecoflex® as an example to disprove the Examiner's inherency theory.

Therefore, the assertion by the Examiner that the disclosed prior art "teaches the sheath to be the same material" claimed by Applicant in claim 142 simply because the prior art discloses polyurethane is incorrect. A skilled artisan knows that different polyurethanes can have different Tg's. Applicants have demonstrated that the polyurethane in the prior art would not necessarily "have the same properties" such as the Tg of claim 142.

With respect to the second basis for inherency, the Examiner has misinterpreted what a Tg is. The Examiner restates the second basis on page 5 of the Examiner's Answer: "it would be inherent for the Tg to be above storage temperature since the sheath would be a solid structure" and "if the Tg were below the storage temperature then the sheath would be a liquid or unstable form during storage." The Tg of a polymer is the point at which the mechanical behavior of the polymer changes from rigid and brittle to tough or plastic. As pointed out in the Appeal Brief on page 5, paragraph 1, many polymers have a Tg below room temperature or a reasonable storage temperature, yet they remain solids and stable. Many polymers with Tg's below room temperature are used at room temperature and remain stable during use. The Applicant cites medical grade polymers such as Tecoflex® which have Tg's (less than -60 °C) below room

temperature and yet are used at room temperature. Therefore, the Examiner's basis for inherency is without merit.

**No prior art cited in the record provides any sort of recognition that a polymer claimed in claim 142 would be suitable as a sheath material**

At page 8, second full paragraph of the Examiner's Answer, the Examiner states she is "not in agreement with Appellant that only applicants have recognized the suitability of polyurethane having a glass transition temperature above a storage temperature of a sheath material." Yet the Examiner argues on page 5 of the Examiner's Answer that such a polymer is not suitable: "if the Tg were below the storage temperature then the sheath would be a liquid or unstable form during storage." The Examiner's argues such a polymer is suitable when arguing the claim is obvious and takes the opposite position regarding suitability to support an argument the claim is inherent.

The Examiner further states (1) "it is well known in the polymer/material art that polyurethane materials are well known" (2) polyurethanes and all materials have properties such as Tg, (3) that storage temperatures range from a variety of temperatures such as cold, warm and hot" and (4) "storage temperatures are temperatures which are desired in transporting or intermediate temperature or final disposition of the product." Applicant agrees that polyurethanes are well known and have Tgs. However, temperature ranges of storage, i.e., (3), and a definition of a storage temperature, i.e., (4), do not provide any sort of recognition that a polyurethane having a Tg above a storage temperature be used as a sheath material. No prior art cited in the Record provides such recognition.



**Claim 143 is not obvious in view of the cited prior art**

The Examiner reiterates the basis for rejecting claim 143 at page 8, third full paragraph by stating that “it is well known in the manufacturing arts that materials are well known to be varied to provide that device with properties are desired by the user. It would be obvious to modify/substitute materials to provide more flexibility.” As pointed out in the Appeal Brief, it is true that skilled artisans know how to modify polymers to change their properties. However, obviousness requires them to know which modifications to make and by how much. This remains beyond the capacity of skilled artisans. The record does not contain any references showing that a skilled artisan, possessing the teachings of Sanhatjian, would immediately envision Applicant’s claimed invention. Further, the record does not contain evidence that non-polar segments provide flexibility and bendability to polymers. With respect to the capacity of skilled artisans, the Examiner is making factual assumptions, which is the same as taking official notice of those facts.

## II. Conclusion

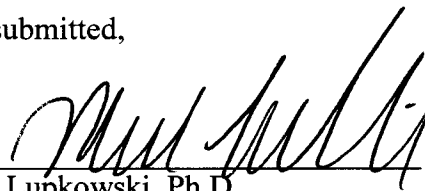
For the foregoing reasons, the rejection of Claims 142, 143, and 147 as being unpatentable under 35 U.S.C. 103 over Sanhatjian is in error, and the Board is respectfully requested to reverse the rejection.

Respectfully submitted,

Date: December 5, 2007

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